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10/695,527	10/28/2003	Richard A. Hines	774317-0002	6401

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EXAMINER	
OU, JING RUI	
ART UNIT	**PAPER NUMBER**
3773	
MAIL DATE	**DELIVERY MODE**
09/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,527	HINES ET AL.	
	Examiner	Art Unit	
	JING OU	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-17,19-21 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-17, 19-21, and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the amendment filed on July 08, 2008. Claims 1-17, 19-21 and 32 are pending. Claim 1 is independent. Claims 18 and 22-31 are cancelled. Claim 32 is newly added.

Information Disclosure Statement

2. The information disclosure statements filed on 10/28/2003 and 01/06/2006 fail to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. U.S. Patent Nos. 6,019,784 is not found in either of the IDS filed on 10/28/2003 and 01/06/2006, and therefore not considered.

Claim Objections

3. Claims 19 and 20 are objected to because of the following informalities: Claims 19 cannot depend on Claim 18 since Claim 18 is cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 5, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boussignac et al (US Pat. No.: 6,056,767) in view of Drasler et al (US Pat. No.: 6,287,335 B1).

In regard to Claim 1, Boussignac et al discloses a pleated stent assembly comprising: a balloon (1, Fig. 1); and a tube (2, Fig. 1) having an original diameter (It is well known in the art that a stent has an original diameter, Col. 4, lines 12-14, and Col. 5 lines 18-19), wherein at least a portion of said balloon is contained within said tube (Fig. 7), wherein said tube and said balloon are co-pleated along longitudinal pleating lines to form a substantially cylindrical pleated tube/balloon assembly (Fig. 1 and Fig. 2 and Col. 2, lines 47-50) having a delivery width, and wherein said delivery width of said assembly is less than said original diameter (It is well known it the art that tube/balloon assembly has a delivery width which is less than its original diameter) of said tube.

Boussignac et al does not appear to disclose the wall of the tube to be comprised of a pattern of interconnected solid area defining open spaces therebetween, wherein the solid area is continuous.

However, Applicant should be noted that it is well known in the art that a stent comprises a pattern of interconnected solid area defining open spaces therebetween, wherein the solid area is continuous. For example, Drasler et al teaches a stent comprises a pattern of interconnected solid area defining open spaces therebetween, wherein the solid area is continuous (Fig. 17C). The interconnected structure of a stent would provide a better structural support for the stent inside a blood vessel. Therefore, it would have been obvious to combine Drasler et al with Boussignac et al to obtain the invention as specified in the instant claim.

In regard to Claim 2, Boussignac et al discloses that the tube is formed from a material (Col. 4, lines 6-7) that undergoes sufficient plastic deformation (Col. 4, lines 4-

5) along said pleating lines (line L, Fig. 7) to substantially maintain said delivery width of said tube/balloon assembly.

In regard to Claim 3, Boussignac et al discloses that the device further comprises a tubular sleeve (cover, Col. 4, line 26) substantially surrounding said tube/balloon assembly (Col. 4, lines 26-30) to substantially maintain said delivery width of said tube/balloon assembly (Col. 4, lines 39-40).

In regard to Claim 5, Boussignac et al discloses that the tube is flexible along its longitudinal axis (Figs. 1-2).

In regard to Claim 18, Boussignac et al discloses that the tube is a stent (2, Fig. 1 and see Abstract).

In regard to Claim 32, Boussignac et al discloses a porous surface layer (cover, Col. 4, lines 31-34) for controlled elution of drug or other substances.

8. Claims 1-14, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drasler et al (US Pat. No.: 6,287,335 B1) in view of Boussignac et al (US Pat. No.: 6,056,767).

In regard to Claim 1, Drasler et al discloses a pleated stent assembly comprising: a balloon (300, Fig. 4E); and a tube having an original diameter (It is well known in the art that a tube/stent has an original diameter), wherein at least a portion of said balloon is contained within said tube (260, Fig. 4E), wherein said tube (260) and said balloon (300) are pleated along longitudinal pleating lines to form a substantially cylindrical pleated tube/balloon assembly (Fig. 4E) having a delivery width (235), and wherein said delivery width of said assembly is less than said original diameter (110, Fig. 4B and Col.

24, lines 30-35) of said tube; wherein a pattern of interconnected solid area defining open spaces therebetween, wherein the solid area is continuous (Fig. 17C).

Drasler et al does not appear to disclose that the tube and the balloon are co-pleated.

However, Boussignac et al explicitly disclose that the tube (Boussignac et al, 2, Fig. 1) and the balloon (1, Fig. 1) are co-pleated (Fig. 7 and Col. 2, lines 47-50).

Drasler et al and Boussignac et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Drasler et al and Boussignac et al before him or her, to modify the pleated stent assembly to have the tube and the balloon co-pleated.

The suggestion/motivation for doing so would have been to ensure a regular spreading out of the stent forming element, guided by the balloon, during its spreading out by inflation (Boussignac et al, Col. 2, lines 61-62)

Therefore, it would have been obvious to combine Boussignac et al with Drasler et al to obtain the invention as specified in the instant claim.

In regard to Claim 2-14, 18, and 20, Drasler further discloses the following:

In regard to Claim 2, the tube is formed from a material (platinum, Col. 8, lines 9-15) that undergoes sufficient plastic deformation (260 and Col. 8, lines 49-53) along said pleating lines to substantially maintain said delivery width of said tube/balloon assembly.

In regard to Claim 3, the device further comprises a tubular sleeve (sheath, 225, Fig. 4E) substantially surrounding said tube/balloon assembly to substantially maintain said delivery width of said tube/balloon assembly.

In regard to Claim 4, the tube is formed from a material having super-elastic properties (Nitinol, Col. 8, lines 9-15).

In regard to Claim 5, the tube is flexible along its longitudinal axis (Col. 6, lines 31-35).

In regard to Claim 6, the wall of said tube comprises at least one substantially solid annular body section (metallic strands, 750, Fig. 23 and Col. 13, lines 7-10)

In regard to Claim 7, the body section is not radially expandable substantially beyond said original diameter upon inflation of said balloon (Col. 6, lines 64-67, Col. 7, lines 1-4 and 10-12).

In regard to Claim 8, the wall of said tube comprises at least one annular anchor section (245, Fig. 5), wherein said anchor section is radially expandable beyond said original diameter upon inflation of said balloon (Col. 11, lines 3-6, 21-22, and 32-39).

In regard to Claim 9, the wall of said tube comprises at least one annular anchor section (245, Fig. 5), wherein said anchor section is radially expandable beyond said original diameter upon inflation of said balloon (Col. 11, lines 3-6, 21-22, and 32-39).

In regard to Claim 10, the wall of said tube is comprised of a pattern of interconnected solid areas defining open spaces therebetween (Fig. 23 and Col. 13, lines 29-31).

In regard to Claim 11, the pattern restricts radial expansion of said tube substantially beyond the original diameter over a portion of the length of said tube (Col. 6, lines 64-67, Col. 7, lines 1-4 and 10-12).

In regard to Claim 12, Drasler et al discloses all the limitations of the claim but fail to disclose the pattern comprises greater than about 60 percent solid area in the portion of the tube wherein radial expansion is restricted. However, Drasler et al explicitly disclose that the gaps or leakage sites (495, Fig. 13C) are small and the size of the gaps or leakage sites is dependent up the monofilament strand diameter (500, Fig 13C) as well as how tightly they are packed. The size of the gaps of leakages sites can be approximately as large as the monofilament strand diameter (Col. 49, lines 16-24). Therefore, it is obvious that the pattern comprises more than 60 percent solid area in the portions of the tube wherein radial expansion is restricted (Col. 57, lines 66-67 and Col. 58, lines 1-2).

The suggestion/motivation for doing so would be to prevent blood cellular elements from passing through the leakage sites. With small leakage sites, red blood cells and platelets can become trapped and create thrombosis that will prevent leakage from that gap of leakage site (Drasler et al, Col. 49, lines 24-29).

In regard to Claims 13 and 14, the pattern allows radial expansion of said tube beyond said original diameter over at least a portion of the length of said tube. The pattern allows radial expansion up to about 130% of said original diameter in the portion of said tube wherein radial expansion is allowed (up by 50% is the same as up to 150%

of the original diameter. This covers the up to about 130% as claimed. Col. 63, lines 51-54)

In regard to Claim 18, the tube is a stent (Fig. 23).

In regard to Claim 21, the tube is formed from a biocompatible plastic (polyester ad polyurethane, Col. 25, lines 4-5)

9. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drasler et al (US Pat. No.: 6,287,335 B1) in view of Boussignac et al (US Pat. No.: 6,056,767) as applied to Claim 10 above, and further in view of Penn et al (US Pat. No.: 6,375,667 B1).

In regards to Claims 15-17, Drasler et al and Boussignac et al disclose all the limitations as taught above. Drasler et al further discloses: A) the wall of the device comprises at least one annular anchor section (245, Fig. 5), wherein the circumferential struts in said anchor section are radially expandable beyond said original diameter (Col. 11, lines 3-6, 21-22, and 32-39). B) the wall of the device comprises at least one annular body section, wherein said body section of said wall are radially non-expandable substantially beyond said original diameter (Col. 6, lines 64-67, Col. 7, lines 1-4 and 10-12).

Drasler et al and Boussignac et al do not appear to disclose the solid areas are comprised of longitudinal struts and interconnected circumferential struts.

However, Penn et al explicitly disclose a device comprised of longitudinal struts (770, Fig. 8) and interconnected circumferential struts (760 and 767, Fig. 8)

Drasler et al, Boussignac et al, and Penn et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Drasler et al, Boussignac et al, and Penn et al before him or her to modify the endoprothesis of Drasler et al and Boussignac et al to include the longitudinal struts and interconnected circumferential struts of Penn et al.

The suggestion/motivation for doing so would have been that longitudinal struts could lead to a very desirable balance of lateral flexibility of the unexpanded stent and radial rigidity of the expanded stent (Penn et al, Col. 3, lines 19-23) while the interconnected circumferential struts could enhance the lateral flexibility of the stent (Penn et al, Col. 10, lines 24-25).

Therefore, it would have been obvious to combine Penn et al with Drasler et al and Boussignac et al to obtain the invention as specified in the instant claims.

10. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boussignac et al (US Pat. No.: 6,056,767) in view of in view of Drasler et al (US Pat. No.: 6,287,335 B1) as applied to Claim 1 above, and further in view of Hines (US Pat. No.: 6,019,784).

In regard to Claims 19-20, Boussignac et al in view of Drasler et al discloses all the limitations as taught above but fails to disclose the tube is formed from an electroformed metal and the metal is gold.

However, Hines explicitly discloses a tube that is formed from an electroformed metal and the metal is gold (Hines, Abstract and Col. 4, lines 53-62)

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Boussignac et al, Drasler et al, and Hines before him or her to modify the tube of Boussignac et al in view of Drasler et al to be formed from an electroformed metal such as gold of Penn et al.

The suggestion/motivation for doing so would have been that electroformed metal such as gold is sufficiently ductile to be radially expandable to form an appropriate intra vascular endoprosthesis and sufficiently rigid to hold its shape once the expansion force is removed (Hines, Col 4, lines 53-57).

Therefore, it would have been obvious to combine Hines with Boussignac et al and Drasler et al to obtain the invention as specified in the instant claims.

Response to Arguments

11. Previous objections to the specification and drawings have been overcome

12. Applicant's arguments filed 07/08/2008 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a balloon stent assembly to be flexible and small enough to make use in the brain feasible, a thin, one piece, one material, ductile pleated stent capable of being plastically deformed in any direction, without kinking or wrinkling, due to novel physical features including inventive stent wall pattern and manufactured material properties, the stent is used to treat aneurysms, and the stent never contains multiple

materials, wires, woven fabric, hinges, or joints) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Boussignac et al does not teach a tube. However, Boussignac et al clearly discloses a tube since the stent (2) is a coiled tube.

13. Currently, the claimed invention or the pleated stent assembly of this application is not patentable distinct from the pleated stent assembly as taught by the combination of prior art references applied above. In addition, Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

14. Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. **Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them**.

15. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/Julian W. Woo/
Primary Examiner, Art Unit 3773